REMARKS

Applicants have received and reviewed a final Office Action dated July 24, 2003. Applicants request entry of this amendment and response and reconsideration of the rejection of the claims.

Applicants have amended claims 1, 7 and 9. Applicants submit the amendments to the claims are supported throughout the specification including at page 4, lines 29-33; page 6, lines 12-32; page 8, lines 1-6; page 12, lines 1-10; and page 25, lines 12-22.

With respect to all amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and have not acquiesced to any objection and/or rejection made by the Examiner. Applicants expressly reserve the right to pursue the canceled subject matter in one or more continuation applications.

Applicants have canceled claims 5-6, 9-14, 17 and 22-95 without prejudice or disclaimer. The Examiner requests that Applicants cancel claims in nonelected groups. Applicants reserve the right to pursue the subject matter of these claims in one or more continuation applications.

Applicants have added new claims 96-101. Applicants submit the new claims are supported throughout the specification including at page 5, line 8 to line 26; and page 7, lines 1-22.

Information Disclosure Statement

The Examiner has indicated that he has not considered the references in the Information Disclosure Statement. The Examiner is recommending the submission of a concise explanation of English language documents. The Examiner cites dicta in the Molins PLC v. Textron Inc., 33 USPQ2d 1823 (1995) case and MPEP § 609 and § 2004.

Applicants respectfully submit that the IDS as submitted is fully compliant with the law and should be considered by the Examiner. As stated in MPEP § 609, the requirement for a concise explanation of relevance is limited to information that is not in the English language. MPEP § 609, p. 600-118 (emphasis added). Applicants also remind the Examiner that MPEP § 2004 indicates that the information presented therein "are offered as examples of possible procedures ", but are not required in order for any

IDS to fully comply with the law. MPEP § 2004, p. 2000-7. Applicants have also reviewed the Molins PLC case, and in that case, the Court actually found no inequitable conduct when a reference was submitted as one of the 94 patent and nonpatent references in an Information Disclosure Statement in accord with 37 CFR § 1.98 (no explanation of relevance necessary for information in the English language). Molins PLC at p.1832. Therefore, Applicants submit that a concise explanation of English language documents is not required for an IDS to be fully compliant with the law and for the Examiner to consider the references.

Thus, Applicants have submitted an Information Disclosure Statement in full compliance with the law and respectfully request that the Examiner consider the cited references and return the initialed PTO 1449 form.

Claim for Domestic Priority

Applicants request that the Examiner acknowledge Applicants' claim for domestic priority under 35 U.S.C. § 119(e) to 60/228,914 filed August 29, 2000, 60/197,089 filed April 14, 2000, and 60/175,849 filed January 13, 2000.

35 U.S.C. § 112, Second Paragraph

Applicants acknowledge the withdrawal of the 35 U.S.C. § 112, second paragraph rejection of claims 1, 4, 9-11, 15-16 and 18-21.

35 U.S.C. § 112, First Paragraph, Enablement

Applicants acknowledge the withdrawal of the 35 U.S.C. § 112, first paragraph rejection, enablement rejection of claims 1, 7, 9, 15-16 and 18-21.

35 U.S.C. § 112, First Paragraph, Written Description

The Examiner has rejected claims 1, 7, 15-16 and 18-21 under 35 U.S.C. § 112, first paragraph. The Examiner contends that an isolated nucleic acid molecule which comprises DNA having at least 80% sequence identity to disclosed sequences do not have sufficient description in the specification as a description of a species is insufficient

to support a highly variable genus. The Examiner further alleges that sequence similarity results in an unpredictable and, therefore, unreliable correspondence between the newly discovered sequence and a similar biomolecule of known function or expression. In addition, the Examiner asserts that describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, which the Examiner acknowledges the example does, does not necessarily describe the cDNA itself. Applicants respectfully traverse the rejection.

The written description requirement requires that Applicants' specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). A written description of an invention involving a chemical genus requires a precise definition, such as by structure, formula ... of the claimed subject matter sufficient to distinguish it from other materials. Univ. of California v. Eli Lilly and Co., 43 USPQ2d 1398. 1405 (Fed. Cir. 1997) (emphasis added). Since one skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass, such a formula is normally an adequate description of the claimed invention. Id. at 1406 (emphasis added). Moreover, as noted in the Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, ¶1, "Written Description" Requirement ("the guidelines"), there is a "strong presumption" that an adequate written description of the claimed invention is present when the application is filed, 66(4) Fed Reg. 1099, 1105 (2001); see also, In re Wertheim, 191 USPQ 90,97 (CCPA 1976). The guidelines further state that "[(The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." 66(4) Fed. Reg. at 1107; 191 USPQ at 97, (emphasis added).

Compliance with the written description requirement does not require an applicant to describe exactly the subject matter claimed; rather, the description must clearly allow a person of ordinary skill in the art to recognize that he or she invented what is claimed. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The test is whether the originally filed specification reasonably conveys to a person having

ordinary skill in the art that applicant had possession of the subject matter later claimed. In re Kaslow, 217 USPQ 1089 (Fed. Cir. 1991). Moreover, in order to have possession of members of a claimed genus, the specification need not describe all of the species that the genus encompasses. Amgen Inc. v. Chugai Pharmaceutical Co., 18 USPQ2d 1016, 1027 (Fed. Cir. 1991).

More specifically, Applicants' claims relate to a genus of nucleic acid molecules which comprise DNA having at least 80% sequence identity to (a) a DNA molecule encoding a PRO10282 polypeptide comprising the sequence of amino acid residues from 1 to 667 of Figure 2 (SEQ lID NO:2), or (b) the complement of the DNA molecule of (a), wherein the isolated nucleic acid is other than murine stra6; or to a genus of nucleic acid molecules comprising DNA which comprises at least 80% sequence identity to (a) the full-length polypeptide coding sequence of the human protein cDNA deposited with the ATCC on January 11,2000 under ATCC Deposit No. PTA-1181 (DNA148380-2827), or (b) the complement of the coding sequence of (a), wherein the isolated nucleic acid is other than DNA encoding murine stra6.

As discussed previously, both the guidelines and the training materials stand for the proposition that the written description requirement under *35* U.S.C. § 112, first paragraph, is satisfied for claims encompassing a genus related to a sequence (e.g. protein X), wherein the sequence is provided, along with a code (e.g. the genetic code) which unambiguously would allow one of skill in the art to determine all of the related sequences which would fall within the scope of the genus, even if only a single specie is disclosed. This proposition is further supported by the Federal Circuit's decision in Univ. of California v. Eli Lilly wherein the court stated that written description for a chemical genus is satisfied when the specification provides a formula "of the claimed subject matter sufficient to distinguish it from other materials" and wherein such formula would allow one of skill in the art to "identify many of the species that the claims encompass". Univ. of California v. Eli Lilly and Co. at 1405, 1406.

Applicants submit that they have provided a structural formula for the claimed invention. More specifically, instant claims 1,7, 15, 16, 18-21 encompass a genus related to a sequence, wherein the sequence is provided, along with a formula which would allow

one of skill in the art to determine all of the related sequences which would fall within the scope of the genus. The specific sequence is SEQ ID NO:2, and the formula, analogous to the genetic code, is a sequence alignment code as described in the specification, for example BLAST, BLAST-2, ALIGN, ALIGN-2 and Megalign (DNASTAR). One of skill in the art, using the specific sequence and a code would be able to unambiguously determine all of the compounds which fall within the scope of the genus of compounds which comprise DNA having at least 80% sequence identity to (a), a DNA molecule encoding a PRO10282 polypeptide comprising the sequence of amino acid residues from 1 to 667 of Figure 2 (SEQ ID NO:2), or (b) the complement of the DNA molecule of (a), wherein the isolated nucleic acid is other than DNA encoding murine stra6; or to a genus of nucleic acid molecules comprising DNA which comprises at least 80% sequence identity to (a) the full-length polypeptide coding sequence of the human protein cDNA deposited with the ATCC on January Il, 2000 under ATCC Deposit No. PTA-l 181 (DNA148380-2827), or (b) the complement of the coding sequence of (a), wherein the isolated nucleic acid is other than DNA encoding murine stra6. As discussed previously, like Example 11 of the training materials, the present invention provides a specie (as depicted within SEQ ID NO:2), which has been fully reduced to practice.

Moreover, whereas the full scope of the genus in the instant claims relates to compounds which comprise DNA having at least 80% sequence identity to (a) a DNA molecule encoding a PRO10282 polypeptide comprising the sequence of amino acid residues from 1 to 667 of Figure. 2 (SEQ ID NO:2), or (b) the complement of the DNA molecule of (a); or to nucleic acid molecules comprising DNA which comprises at least 80% sequence identity to (a) the full-length polypeptide coding sequence of the human protein cDNA deposited with the ATCC on January 11, 2000 under ATCC Deposit No. PTA-1181 (DNA148380-2827), or (b) the complement of the coding sequence of (a), in contrast, compounds falling within the scope of claims similar to claim 1 as described in Example 11 of the training materials might exhibit only about 67% sequence identity. Thus, the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for a protein. In re Bell at 1532. Nevertheless, even though an enormous number of compounds might fall within the scope of claim 1 from

Example 11 of the training materials, the written description requirement was deemed satisfied.

Therefore, in view of the fact that the guidelines, the training materials and several Federal Circuit decisions (e.g., In re Bell; In re Baird) determined that claims similar to claim 1 of Examples 9 and 11 of the training materials do not violate the written description requirement, Applicants submit that the instant claims also do not violate the written description requirement. More specifically, the instant specification would convey with reasonable clarity to those skilled in the art that, as of the filing date, Applicants were in possession of the claimed subject matter. The law, as articulated by the Federal Circuit, requires no more. See, Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

The Examiner contends that the claims are not drawn to a genus of polynucleotides encoding a particular protein, but Applicants submit that the written description does not require that the isolated nucleic acid molecule encode a particular protein, but only that description allow one of skill in the art to distinguish it from other materials. Applicants submit they have described the isolated nucleic acid sequences sufficiently to allow one of skill in the art to distinguish the claimed subject matter. As discussed above, Applicants have described and provided a structural formula for a species which has been fully reduced to practice. Applicants have also described a naturally occurring variant as shown in Figures 6 and 7 (SEQ ID NO:4) that has about 99% nucleotide sequence identity to SEQ ID NO:1. In Figure 8, Applicants have provided alignment of SEQ ID NO:2 with murine stra6 sequence and the variant sequence. The alignment between amino acid sequence (SEQ ID NO:2), the variant (SEQ ID NO:4), and the murine stra6 sequence identifies regions of high homology of the molecule. In addition, Applicants have directed one of skill in the art to align the sequence of SEQ ID NO:2 with that of homologous known protein molecules and minimize the number of amino acid sequence changes made in regions of high homology. (See the specification at page 46, line 28 to page 47, line 6). Such alignment can be readily conducted with the murine stra6 sequence and variant stra6 sequence as provided by Applicants.

Thus, Applicants submit that they have provided sufficient characterization of the claimed nucleic acids to distinguish them from other materials, and respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph, rejection.

35 U.S.C. § 102

The Examiner rejected claims 1, 7 and 9-11 under 35 U.S.C. § 102(a) as allegedly anticipated by a sequence of Database GenEmbl Accession No. AF062476. The Examiner contends that the reference sequence shows 82.59% identity with a nucleic acid sequence encoding protein SEQ ID NO:2. The Examiner also contends that, in regards to claims 9-11, the referenced sequence has continuous stretches matching the claimed nucleotide so that it will hybridize to nucleic acid residues encoding residues 1-667 of protein SEQ ID NO:2. Applicants respectfully traverse.

As an initial matter, Applicants read the provided alignment with AF062476 to show a % similarity value and not a % identity value. Applicants note that a % similarity value is not a value used in comparisons of nucleotide sequences but rather with amino acid sequences. As understood by those of skill in the art, %similarity describes the relationship between two amino acid sequences including identical amino acids as well as those that are similar in properties. Typically, a % similarity value is much higher than a % identity value for amino acid sequences.

However, without acquiescing to the Examiner's rejection and solely to expedite prosecution , Applicants have amended claims 1 and 7. Applicants' claims 1 and 7 now recite that the isolated nucleic acid molecule is other than DNA encoding murine stra6. Applicants claim 9 now is directed to an isolated nucleic acid that encodes a PRO10282 polypeptide, wherein the PRO10282 polypeptide is different from a murine stra6 polypeptide.

Applicants submit that claims 1 and 7 now recite the isolated nucleic acid is other than a DNA encoding murine stra6. The DNA sequence of Database GenEmbl Accession No. AFO62476 encodes murine stra6 and thus, for at least this reason, Applicants submit that Database GenEmbl Accession No. AFO62476 does not anticipate claims 1 and 7. Applicants respectfully request withdrawal of the rejection on this basis.

Applicants submit that claim 9 now recites the isolated nucleic acid molecule that encodes a PRO10282 polypeptide different from a murine stra6 polypeptide. The DNA sequence of Gen Embl Accession No. AF062476 encodes murine stra6, and thus, for at least this reason, Applicants submit that Database GenEmbl Accession No. AF062476 does not anticipate claims 9-11. Applicants respectfully request the withdrawal of the rejection on this basis.

35 U.S.C. § 102

The Examiner rejected claims 9-11 under 35 U.S.C. § 102(a) as allegedly anticipated by the sequence of Database GenEmbl, Accession No. AAV84436. The Examiner alleges that the alignment covers nucleotides 1768-2663 not 1768-2049 as indicated by Applicants. Applicants respectfully traverse.

Applicants claim 9 now recites an isolated nucleic acid that encodes a PRO10282 polypeptide comprising DNA that hybridizes to the complement of the nucleic acid sequence that encodes amino acids 1 to 667 of Figure 2 (SEQ ID NO:2), wherein the PRO10282 polypeptide is at least 100 amino acids in length. Applicants understand that the provided alignment for AAV84436 concerns nucleotides 1768-2663, however, Applicants point out that that the coding sequence of SEQ. ID. NO: 1 is from about nucleotide 49 to 2049. The portion of the alignment that involves the coding sequence for an embodiment of a PRO10282 polypeptide is from about nucleotide 1768 to 2049. This portion of the alignment would encode a PRO polypeptide with less than 100 amino acids. Thus, Applicants submit for at least this reason, Gen Bank Accession No. AAV84436 does not anticipate claims 9-11.

Based on the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(a) rejection.

Summary

Applicants submit that all pending claims are in condition for allowance, and notice to that effect is earnestly requested. The Examiner is invited to contact Applicants' representative at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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